

Application No. 10/679,888
Docket No. A4-1765
Reply dated January 25, 2008
In Response to Official communication dated November 27, 2007

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Amendments to the Specification:

Please replace the title of the invention at page 1 with the following amended title:

A SYSTEM FOR MONITORING PULMONARY ARTERY
PRESSURE ~~IN PATIENTS WITH PULMONARY~~
~~HYPERTENSION~~

Please replace the two paragraphs under the section "Summary of the Invention" with the following two amended paragraphs:

The invention comprises a telemetric sensing system for noninvasively monitoring cardiac physiologic parameters used to evaluate patients with pulmonary hypertension. The system includes an implantable sensor unit and a companion reader unit. The ~~batteryless, wireless pressure~~ sensor unit, which is preferably batteryless and wireless, is configured to be chronically ~~is~~ ~~chronically~~ implanted in any of several locations in the heart (e.g. right ventricle (RV), right atrium (RA), pulmonary artery (PA)). The

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sensor unit ~~implant~~ may be delivered percutaneously (for example, by catheter), surgically, and/or on a stent. Once in place, the sensor unit ~~implant~~ may be wirelessly interrogated with the reader unit.

Upon placement in the respective locations in the heart, the sensor unit ~~implant~~ is capable of measuring and transmitting, in real time, any of various physiologic parameters including RV, RA, PA, and related pressures. This approach would be the preferred way to noninvasively monitor the response of pulmonary artery hypertension to different treatments. Monitoring one or more of these parameters gives the physician several advantages:

- Facilitates earlier intervention in the course of disease; ~~disease~~
- Enables better tailoring of medications or other treatments and therapies to reduce pulmonary hypertension; ~~hypertension~~
- Facilitates the identification of other complications from treatments or disease progression; ~~progression~~
- Gives faster feedback on the impact of medications and/or pacing changes on heart function; ~~function~~

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- Facilitates pacemaker parameter tuning; ~~tuning~~
- Lowers overall treatment costs; ~~and/or costs~~
- Decreases frequency and/or severity of hospitalization for pulmonary-hypertension-related conditions through improved outpatient and home care; ~~care~~

Please add the following new paragraph at the end of the "Summary of the Invention":

Other objects and advantages of this invention will be better appreciated from the following detailed description.

Please replace the first full paragraph on page 4 with the following amended paragraph:

In order to provide for the effective monitoring, management, and tailoring of treatments for pulmonary hypertension, the present invention provides a telemetric ~~wireless~~ sensing system. The system comprises an implantable ~~pressure~~ monitor in the form of

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an implant 50 which may have a cylindrical shape as shown in Figure 4 and can be ~~is~~ securely anchored in the pulmonary artery as shown in Figure 1 or in a cavity of the heart as shown in Figure 5, ~~as shown in Figure 1,~~ and an external readout unit represented in Figures 2 and 3. The readout unit both transmits power to and receives transmitted data from the implant 50 through a wireless telemetry link. Data transmitted from the implant 50 ~~implantable device~~ may include pressure, temperature, calibration data, identification data, fluid flow rate, chemical concentration, and/or other physiologic parameters. The readout unit may include a barometric pressure sensor in order to compensate for variation in atmospheric pressure.

Please replace the second full paragraph on page 4 with the following amended paragraph:

In the preferred embodiment, the implant 50 ~~sensor~~ transmits data corresponding to PA, RA, RV, LA (left atrium), LV (left ventricle), dp/dt, and/or the entire RA, PA, RV, LV, or LA waveform

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can be useful to evaluate pulmonary hypertension. To accomplish this, the implant 50 ~~sensor~~ is located such that it reads the pressure of interest, typically in the PA, RV, RA, LV or LA as appropriate. Note that the implant 50 ~~sensor~~ may be located directly in the cavity whose pressure is being monitored, or it may be located in an intermediary structure, such as the atrial or ventricular septum, as long as communication with the parameter of interest is maintained.

Please replace the paragraph bridging pages 4 and 5 with the following amended paragraph:

The ~~batteryless, wireless~~ telemetry link between the implant 50 and the readout unit is preferably batteryless, wireless, and implemented using either a resonant or passive, magnetically coupled scheme. A resonant device 101 (shown in Figure 2) is the simplest approach, and consists only of a packaged inductor coil 103 and capacitive pressure sensor 102. Together, the sensor 102 and coil 103 ~~two elements~~ form a circuit that has a specific resonant frequency. At that resonant frequency, the circuit presents a

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measurable change in magnetically coupled impedance load to an external coil 105 associated with an external reader 104. Because the resonant frequency is a function of the ~~coil~~ inductance of the coil 103 and the ~~sensor~~ capacitance of the sensor 102, as pressure changes the resonant frequency changes as well. The external ~~An external~~ reader 104 is able to determine pressure by monitoring the frequency at which the coil antenna 105 impedance changes.

Please replace the first full paragraph on page 5 with the following amended paragraph:

The preferred communication scheme for the present invention, shown in Fig. 3 as being between a passive implant device 201 and an external reader 202, is based on magnetic telemetry. Devices that have on-board circuitry but still receive their operating power from an external source (i.e., are batteryless) are referred to herein as passive. Without the external reader 202 ~~passive devices 201 (shown in Figure 3). Without an external reader present, the~~ implant device 201 lays passive and without any internal means to

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power itself. When a pressure reading is desired, the reader ~~device~~ 202 is brought into a suitable range to the implant device 201. In this case the external reader 202 uses an alternating magnetic field to induce a voltage in the implant device 201. When sufficient voltage has been induced in the implant device 201, a rectification circuit 203 converts the alternating voltage on the receiver coil 204 into a direct voltage that can be used by the electronics 205 as a power supply for signal conversion and communication. At this point the implant device 201 can be considered alert and, in the preferred embodiment, also ready for commands from the reader 202. The maximum achievable distance is mostly limited by the magnetic field strength necessary to turn the implant device 201 on. This telemetry scheme has been proven and used extensively in the identification and tracking industry (e.g., implantable RF ID technology from Texas Instruments or Digital Angel) with a great deal of acceptance and success.

Please replace the paragraph bridging pages 5 and 6 with the following amended paragraph:

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Once the direct voltage in the implant device 201 has been established for the circuit operation, a number of techniques may be used to convert the ~~sensor~~ output of the device 201 into a form suitable for transmission back to the reader 202. ~~device~~ In the preferred embodiment, a capacitive pressure sensor 206 and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do suffer in this application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

Please replace the second full paragraph on page 6 with the following amended paragraph:

In addition to the many available modulation techniques, there are many technologies developed that allow the implant device 201

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to communicate back to the reader 202 the signal containing pressure information. It is understood that the reader 202 ~~device~~ may transmit either a continuous level of RF power to supply the ~~implant's~~ needed energy for the device 201, or it may pulse the power allowing temporary storage in a battery or capacitor device (not shown) within the device 201. Similarly, the implant device 201 of Fig. 3 may signal back to the reader 202 at any interval in time, delayed or instantaneous, during reader RF (Radio Frequency) transmission or alternately in the absence of reader transmission. The implant device 201 may include a single coil antenna 204 for both reception and transmission, or it may include two antennas 204 and 221, one each for transmission ~~204~~ and reception, respectively. ~~221~~. There are many techniques for construction of the reader coil 219 and processing electronics known to those skilled in the art. The reader 202 may interface to a display, computer, or other data logging devices 220.

Please replace the third full paragraph on page 6 with the following amended paragraph:

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The electronic circuit may consist of the coil antenna 204, ~~a receiving inductor coil 204~~, rectification circuitry 203, signal conditioning circuitry 211, and signal transmission circuitry 212.

Please replace the paragraph bridging pages 6 and 7 with the following amended paragraph:

A large number of possible geometries and structures are available for the coil 204 and are ~~receiver coil and~~ known to those skilled in the art. The coil conductor may be wound around a ferrite core to enhance magnetic properties, deposited on a flat rigid or flexible substrate, and formed into a long/skinny or short/wide cylindrical solenoid. The conductor is preferably made at least in part with a metal of high conductivity such as copper, silver, gold. The coil 204 ~~coil~~ may alternately be fabricated on implantable sensor substrates. Methods of fabrication of coils on the sensor substrate include but not limited to one or more or any combination of the following techniques: sputtering, electroplating, lift-off, screen printing, and/or other suitable methods known to those skilled in the

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art.

Please replace the paragraph bridging pages 7 and 8 with the following amended paragraph:

The signal transmission circuitry 212 transmits the encoded signal from the signal conditioning circuitry 211 ~~circuitry~~ for reception by the external reader 202 ~~an external reader~~. Magnetic telemetry is again used for this communication, as the transmission circuitry 212 generates an alternating electromagnetic field that propagates to the reader 202. Either the same coil 204 is used for signal reception and for transmission, or alternately the second coil 221 ~~a second coil 221~~ is dedicated for transmission only.